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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/500,991 | 02/15/2000 | Frank Uhlmann | 0652.2040000/REF | 3282 |

7590 05/18/2006

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| EXAMINER |
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FRONDA, CHRISTIAN L

| ART UNIT | PAPER NUMBER |
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1652

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--|---------------------------------------|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | Application No. 09/500,991 | Applicant(s) UHLMANN ET AL. | |
| | Examiner Christian L. Fronda | Art Unit 1652 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 March 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: 59.

Claim(s) rejected: 36,37,40,41,43,44,46-49 and 59.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☐ Other: _____.

Continuation of 3. NOTE: Claims 36, 37, 40, 41, 43, 44, 46-49, 58 would be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicants amendment and arguments filed 03/30/2006 have been fully considered but are not persuasive.

The claims are genus claims that encompass a genus of peptides of any amino acid sequence, structure, and biological function comprising the amino acid sequence EXXR, where X is any amino acid; comprising the amino acid sequence of SEQ ID NO: 1, a or human SSC1 or fragment or variant thereof. The scope of the genus is not limited to peptides consisting of EXXR, SEQ ID NO: 1, or human SSC1 since the claims specifically recite the phrase "comprising an amino acid sequence".

The specification does not disclose how the length or the composition of the of the peptide containing EXXR would affect the ability of the separase to recognize and hydrolyzes the peptide. The specification does not disclose where the EXXR should be in relation to the N- or C-terminal of the peptide which will enable the separase to recognize and hydrolyze the peptide. It is not clear from the specification if large peptides comprising EXXR would be hydrolyzed by separase. It is not clear from the specification that SEQ ID NO: 1 or human SSC1 is representative of the entire claimed genus of peptides having EXXR, where the claimed genus encompass any peptide comprising any number of amino acid residues including modified and non-naturally occurring amino acid residues. Thus, the skilled artisan cannot predict the structure of other peptides which are separase substrates as encompassed by the claimed genus. Thus, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed genus of peptides of any amino acid sequence, structure, and biological function comprising the amino acid sequence EXXR, where X is any amino acid comprising the amino acid sequence of SEQ ID NO: 1, a or human SSC1 or fragment or variant thereof.

Example 18 of the USPTO's Synopsis of Application of Written Description Guidelines" is not directed toward an assay method using a genus of substrates comprising the amino acid sequence EXXR. Example 18 is only directed toward a method of expressing a protein of interest in *Neurospora crassa* mitochondria. Thus, applicants' argument that the claimed invention meets the written description requirement in view of Example 18 of the Patent Office's Written Description Guidelines is not accurate.

Thus, one skilled in the art cannot visualize or recognize the identity of the members of the genus for use in the claimed method. In view of these considerations, one of skill in the art would not recognize that applicants were in possession of the claimed invention.



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